

APPARATUS AND METHODS FOR TREATING SLEEP APNEA

Related Applications

This application claims the benefit of U.S. 5 provisional application No. 60/436,945 filed on December 30, 2002, and U.S. provisional application No. 60/437,058 filed on December 30, 2002, the entire disclosures of which are incorporated herein by this specific reference.

10

Background of the Invention

The present invention generally relates to apparatus and methods for treating sleep apnea and/or related breathing disorders, and more specifically 15 relates to apparatus for placement in the oropharyngeal region of a human or animal and methods using such apparatus for treating sleep apnea and/or snoring.

Sleep apnea is a sleep-related breathing disorder that is thought to affect between 1-10% of the adult 20 population. Recent epidemiologic data indicate that 2% of women and 4% of men between the ages of 30 and 60 years meet the minimum diagnostic criteria for sleep apnea syndrome, representing more than 10 million individuals in the United States. It is a disorder with 25 significant morbidity and mortality, contributing to increased risk of hypertension, cardiac arrhythmias, stroke, and cardiovascular death. Another common sleep-related breathing disorder is snoring, which may be associated with or independent of sleep apnea.

30 The present invention has been developed to aid in the treatment of snoring and/or the various degrees of

hypopnea and apnea that occur due to pathological disturbances in the sleep process. One of the main reasons of the sleep disturbance is the relaxation of
35 the tongue and pharyngeal walls to varying degrees during the several stages of sleep. When fully awake, these tissues have normal tone as air passes in and out of the lungs during respiration. However, during sleep, the musculature supporting these tissues relaxes. As
40 air is inspired, the tongue and posterior walls of the pharynx collapse, causing snoring or more seriously, causing partial or complete obstruction of the airway.

Obstructive sleep apnea occurs due to a collapse of soft tissue within the upper airway during sleep. The
45 ongoing force of inspiration serves to generate increasingly negative pressure within the pharynx, causing further collapse. The lack of respiration results in inadequate blood oxygenation, and rising carbon dioxide levels. The cardiovascular response produces an increase in the blood pressure and pulse. Cardiac arrhythmias often occur. The carbon dioxide increase and oxygen desaturation triggers a transition to a lighter sleep stage, usually without wakefulness. This transition brings a return to tonicity of the
55 muscles of the upper airway, allowing normal breathing to resume. The person then returns to deeper stages of sleep and the process is repeated. The disease is quantified in terms of respiratory disturbances per hour. Mild disease begins at ten per hour, and it is not uncommon to find patients with indices of about one hundred or more.

Not surprisingly, sleep is extremely fragmented and of poor quality in persons suffering from sleep apnea. As a result, such persons typically feel tired upon 65 wakening and may fall asleep at inappropriate times during the day. All aspects of quality of life, from physical and emotional health, to social functioning are impaired by obstructive sleep apnea.

Continuous Positive Airway Pressure ("CPAP"), 70 disclosed for example in U.S. Patent No. 5,065,756, is a popular non-surgical treatment for patients suffering from sleep apnea. The disclosure of this patent is incorporated in its entirety herein by reference. CPAP is administered by means of a mechanical unit that 75 delivers pressurized room air to the nasal passage, or airway, through a nose mask that is worn by the patient during sleep. Pressurized air enters from the CPAP unit through the nose when a person is sleeping, and opens the airway from the inside almost as if the air were an internal splint. The correct pressure for the individual 80 is determined in a sleep laboratory. If the nasal airway will admit the flow of air, CPAP has in many cases offered immediate relief. Unfortunately however, compliance with, and long-term acceptance of this 85 treatment are generally poor. Studies have shown that between 20% and 50% of patients fail to use nasal CPAP as prescribed. Problems associated with CPAP include excessive dryness of the mouth and throat, mucous congestion, sinusitis, and rhinorrhea. Breathing against 90 positive air pressure is also discomforting to many patients.

Other non-surgical treatments for sleep apnea include the use of tongue retaining devices and other oral appliances that hold and/or pull the tongue or jaw in a forward position to open the airway by reducing 5 collapse of the soft palate and/or tongue. These devices also suffer from poor compliance rates, and are usually associated with degenerative changes in the temporomandibular joint.

Surgical procedures have been proposed and 10 practiced for the treatment of moderate to severe sleep apnea. Uvulopalatopharyngoplasty ("UPPP") is a surgical procedure used to treat obstructive sleep apnea. In UPPP, any remaining tonsillar tissue and a portion of soft palate is removed. The procedure increases the 15 width of the airway at the throat opening. However, UPPP does not address apnea caused by obstructions deeper in the throat and airway, for example, apnea resulting from collapse of tissue near the base of tongue or in the oropharyngeal region of the airway.

20 LAUP, or Laser-Assisted Uvulopalatoplasty, is a modification of the above-mentioned technique, but has not proven particularly useful for sleep apnea. These surgical techniques are extremely invasive, requiring general anesthesia, and a prolonged, painful recovery.

25 Radio frequency tissue ablation (RFTA) with the trade name "Somnoplasty", has been used to shrink the soft palate, uvula and reduce tongue volume in the treatment of snoring and obstructive sleep apnea. Somnoplasty utilizes a radiofrequency tool that 30 generates heat to create coagulative lesions at specific locations within the upper airway. The lesions created

D-3077

by the procedure are naturally resorbed in approximately three to eight weeks, reducing excess tissue volume and increasing the airway opening. Like UPPP and LAUP, more than one session is typically required and it does not 5 address sleep apnea resulting from tissues deeper in the throat than the upper airway.

Another area of surgical interest lies in techniques designed to pull the tongue anteriorly. The most recent such surgical system designed to treat 10 snoring (as well as obstructive sleep apnea) was approved by the FDA in February 1998. Known as the tongue suspension procedure (with the trade name Repose), it is intended to pull the tongue forward, thereby keeping the tongue from falling into the airway 15 during sleep. The system utilizes a bone screw inserted into the mandible. The screw attaches to a non-absorbable suture which travels the length of the tongue and back. Similarly, the hyoid bone can be drawn anteriorly with two distinct screws, also attached to 20 the mandible.

Techniques have also been developed for treating, specifically, the condition of snoring. Conrad et al., U.S. Patent No. 6,250,307 discloses a method for treating snoring of a patient, which includes embedding 25 an implant into a soft palate of a patient in order to alter a dynamic response of a soft palate to airflow. The methods of Conrad et al. are specifically designed to reduce the audibility of snoring but do not address the more serious condition of sleep apnea.

30 These conventional devices and treatments continue to suffer poor cure rates. The failures lie in their

D-3077

inability to maintain patency in the retropalatal region and retroglossal region (the caudal margin of the soft palate to the base of the epiglottis). The poor success rates combined with high morbidity, contribute to an
5 ongoing need for more effective treatments for sleep apnea and/or snoring.

Summary of the Invention

Accordingly, the present invention provides
10 apparatus and methods effective to treat, for example, to substantially eliminate or at least reduce the occurrence of, sleep apnea and/or snoring, meaning to include snoring and/or other sleep-related breathing disorders. The apparatus and methods are relatively
15 straightforward to structure and use, are minimally invasive and provide substantial benefits over conventional techniques in controlling sleep apnea and/or snoring.

In one broad aspect, the present invention provides
20 apparatus comprising an appliance sized and structured to be permanently (that is, for long term usage or for a relatively long time, such as at least about 1 week or about 1 month, preferably at least about 6 months, more preferably at least about 1 year, even more preferably
25 about 5 years or longer) or temporarily implanted or placed in an oropharyngeal region of a human or animal.

The present apparatus may comprise any material or materials suitable for placement in the pharyngeal region which are effective to stiffen, reinforce and/or
30 strengthen tissues of the region in order to provide support to these tissues against collapse such that a patient can breathe more effectively than the patient

would breathe without the material or materials placed in the region.

In one embodiment of the invention, the apparatus generally comprise an appliance sized and structured to be placed in a given position in the oropharyngeal region, other than to facilitate a surgical procedure, and to be effective, when placed in the given position, to treat sleep apnea and/or snoring in a human and or animal (hereinafter, sometimes "patient"). In addition, 10 the appliance is structured to be effective, when so placed, to provide at least one additional benefit relative to a different device that is sized and structured for placement in a position in the patient other than in the given position in the oropharyngeal 15 region. Preferably, the appliance is structured to provide an enhanced compliance with normal, healthy functioning of the oropharyngeal region of a patient relative to such a different device, for example, a stent that is not specifically structured to be utilized 20 for treatment of sleep apnea. For example, the apparatus is structured to have an enhanced, relative to such a different device, ability to be tolerated, preferably comfortably tolerated, by the human or animal while the apparatus is in the given position in the 25 oropharyngeal region, such as when the human or animal is awake or is naturally sleeping.

The appliance of the present invention is advantageously structured to have an enhanced, relative to such a different device, ability to provide support 30 against collapse of the oropharyngeal region during natural sleep, as well as to allow proper closure of an airway in the oropharyngeal region during swallowing.

Preferably, the appliance is sized and structured so that, when so placed in the given position, in the oropharyngeal region, the appliance is located substantially entirely within the pharyngeal region

5 including, preferably, the oropharyngeal region. The apparatus is sized and structured to be temporarily placed in the given position or to be placed in the given position on a relatively long term basis for example, as described elsewhere herein. In addition,

10 the appliance is preferably structured to resist migration within the oropharyngeal region or outside the oropharyngeal region.

In one embodiment of the invention, the appliance comprises a substantially flat or planar member, when

15 located outside the body in a resting or at rest position, including spaced apart end portions and a body portion joining the end portions. In this embodiment of the invention, the apparatus preferably is designed such that when the apparatus is appropriately positioned in

20 the given position, the appliance takes on a curved configuration with end portions bearing against and supporting against collapse, the lateral walls of the oropharyngeal region. The appliance may be sized and structured such that when the apparatus is appropriately

25 placed in the given position, the end portions are spaced apart anteriorly of the posterior wall of the oropharyngeal region, for example, by a portion of the anterior wall of the oropharyngeal region. Preferably, the appliance expands to form an effective diameter of

30 about 32 mm or greater in order to adequately expand to fill the oropharyngeal region

Advantageously, the apparatus is structured to

facilitate removal thereof from the oropharyngeal region. For example, the apparatus may be structured such that when the apparatus is in other than the deployed configuration, for example, when the apparatus
5 is located outside an oropharyngeal region of a human or animal or outside the body of the human or animal in a resting position, the appliance comprises a member that has a flexibility and resiliency that allows the appliance to be folded, rolled or coiled to take on a
10 relatively smaller radius for facilitating insertion thereof into the oropharyngeal region, for example, through the mouth or oral cavity of the patient. When released into the pharyngeal region, the appliance unfolds, unrolls or uncoils, and provides pressure
15 against one or more portions of the pharyngeal region, providing support thereto and maintaining or achieving patency of the pharyngeal region, for example, whether the patient is awake or is naturally sleeping.

The appliance is preferably sized and structured to
20 allow substantially natural functioning of the oropharyngeal region and the epiglottis when the appliance is located in the given position in the pharyngeal region of the patient.

It will become apparent that various configurations
25 of the apparatus are possible to achieve one or more of the benefits of the present invention in treating, e.g. controlling, sleep apnea and/or snoring, and it is to be appreciated that each of such various configurations, for example, the herein disclosed various configurations
30 and modifications thereof, are considered to be within the scope of the present invention. Such configurations include, but are not limited to, an appliance having a

substantially elliptical configuration, a substantially circular configuration, a substantially rectangular configuration, a substantially cylindrical configuration, a substantially linear configuration, a
5 substantially cross-shaped configuration, a substantially C-shaped configuration, a substantially cuff shaped configuration, a substantially coil shaped configuration and the like configurations and combinations thereof. For example, in a more specific
10 embodiment of the invention, the appliance comprises, in a rest position outside the body of a human or animal a substantially flat, flexible, elliptical member having rounded end portions, a length defined between the end portions, and a body portion comprising a plurality of
15 spaced apart struts extending along at least a substantial portion of the length between the end portions.

Preferably, in all embodiments of the invention, the appliance, when located in the oropharyngeal region, 20 has a resiliency and flexibility, for example, resiliency and/or flexibility in at least one direction or at least two different directions or at least three different directions, that enables the appliance to provide an appropriate amount of support and
25 reinforcement to oropharyngeal tissues during natural sleep, while enabling substantially normal functioning of the oropharyngeal region and the epiglottis, for example, during swallowing.

The appliance preferably comprises an elastic material. More preferably, the appliance comprises a super-elastic material. A number of suitable elastic and super-elastic materials are well known and can be
30

employed in the present apparatus. One particularly useful material is a nickel titanium alloy, known as Nitinol. The appliance preferably has a hoop strength effective to support the oropharyngeal region against 5 collapse during natural sleep. More preferably, the appliance has a hoop strength in a range of at least about 5 cm water to about 400 cm water or greater.

The apparatus advantageously comprises an appliance sized and structured to be placed in a position in the 10 oropharyngeal region in proximity to the epiglottis, other than to facilitate a surgical procedure, effective in treating sleep apnea and/or snoring. The appliance is sized and structured to substantially entirely fit within the oropharyngeal region when placed in position. 15 A portion of the device may also be considered to extend above the oropharyngeal region along the posterior portion of the pharynx.

In another broad aspect of the invention, the apparatus for treating sleep apnea and/or snoring 20 comprises an element placed within the oropharyngeal region that is effective, when so placed, to stiffen, reinforce and/or strengthen tissues within the oropharyngeal region in order to support these tissues against collapse and allow substantially normal 25 breathing during sleep.

For example, the element may comprise at least one strip of material that is structured to be placed within the walls of the pharyngeal region. For example, the element may comprise multiple strips of material that 30 are structured and suitable to be implanted within the oropharyngeal tissues, for example, beneath the mucosal tissue, for example, in a spaced apart, substantially

horizontal fashion.

- In a related aspect of the invention, a method for treating sleep apnea and/or snoring comprises the steps of securing one or more elements to the pharyngeal region and allowing the elements to provide an opening force against the pharyngeal walls, such opening force being sufficient to reinforce the walls against collapse during natural sleep while allowing substantially normal functioning of the oropharyngeal region.
- 5 Preferably the method comprises placing at least partially submucosally, within the pharyngeal region of a patient, an appliance effective, when so placed, to maintain patency of the pharyngeal region.
- 10 Preferably, the step of placing comprises placing the apparatus substantially entirely submucosally, preferably in the oropharyngeal region.
- 15 The apparatus, in accordance with an especially advantageous embodiment of the invention, is sized to be placed, at least partially, circumscribing an interior hollow passage defined by the pharyngeal region, for example the oropharyngeal region. In a related aspect of the invention, the appliance is sized to be placed circumscribing, at least once, the interior hollow passage defined by the pharyngeal region.
- 20 25 In another embodiment of the invention, the element may comprise an element that provides a magnetic opening force against collapsing pharyngeal, for example, oropharyngeal, tissues. For example, the element may comprise an appliance, such as described and shown elsewhere herein, that is at least partially magnetized. More specifically, the element may comprise two or more magnetic elements having like poles facing one another,
- 30

D-3077

to create a magnetic field that can be utilized to provide a useful opening force to the pharyngeal, for example, oropharyngeal, region.

Methods for treating sleep apnea and/or snoring in 5 a human or an animal having an oropharyngeal region are provided. In one aspect of the invention, the methods generally comprise providing an appliance, such as described elsewhere herein, in the oropharyngeal region of the human or animal. The appliance, located in the 10 oropharyngeal region, is effective in treating sleep apnea and/or snoring during natural sleep of the human or animal.

In one embodiment, the step of providing includes placing an appliance in the oropharyngeal region that is 15 effective in maintaining patency of the oropharyngeal region during natural sleep of the human or animal. Preferably, the appliance is effective in maintaining patency without causing substantial interference with one or more natural functions of the oropharyngeal 20 region or the epiglottis. For example, the appliance may be structured, when placed in the pharyngeal region, to be effective to support the tissues of the oropharyngeal region against collapse while allowing the oropharyngeal region to close and/or otherwise function 25 consistent with normal swallowing. The apparatus is designed so that, when the appliance is placed in the pharyngeal region it is effective in supporting and holding the lateral walls of the oropharyngeal region in an open position, and/or in supporting and holding the 30 tongue of the patient in a forward position, for example, during natural sleep of the patient.

In yet another embodiment of the invention, a

D-3077

method is provided for maintaining patency of a pharyngeal region of a human or an animal during natural sleep. The method generally comprises the steps of providing a member in a substantially flat or precurved configuration, the member having a body portion and end portions spaced apart by the body portions, and implanting the member, at least partially submucosally, within the pharyngeal region.

Advantageously, the member is effective to provide a substantially constant force against at least a portion of each of a right and left lateral wall of the pharyngeal region.

For example, the step of implanting comprises implanting the member into pharyngeal region such that the member is substantially entirely submucosally implanted therein.

In yet another related embodiment of the invention, a method for maintaining patency of a pharyngeal region of a human or animal during natural sleep and for purposes other than surgery is provided wherein, the method generally comprises the steps of causing a tissue reaction of a pharyngeal region of the patient, said tissue reaction being effective in at least one of strengthening and stiffening lateral walls of the pharyngeal region. For example, the step of causing a tissue reaction may comprise applying an active agent to the walls of the pharyngeal region or, for example, placing at least one member into the lateral walls.

Preferably, the step of providing may include inserting the appliance into the oropharyngeal region, for example through the mouth or oral cavity of the patient, or alternatively, through the nasal cavity of

D-3077

the patient, while the appliance is in a first configuration and, thereafter, allowing the appliance to reconfigure to a second configuration within the oropharyngeal region.

5 In yet another aspect of the invention, a method for treating sleep apnea and/or snoring comprises causing a tissue reaction in an oropharyngeal region of a patient. Such tissue reaction is effected to cause sufficient stiffening and/or strengthening of targeted
10 oropharyngeal tissues in order to substantially reduce the occurrence of collapse of those tissues during natural sleep of the patient.

For example, the step of causing a tissue reaction may comprise one of injecting a suitable agent into the
15 tissues, applying wave energy to the tissues and/or causing mechanical irritation to the tissues in order to provoke a strengthening response.

Each and every feature described herein, and each and every combination of two or more of such features,
20 is included within the scope of the present invention provided that the features included in such a combination are not mutually inconsistent.

These and other aspects of the present invention are apparent in the following detailed description and
25 claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

Brief Description of the Drawings

30 Fig. 1 shows a side view of an apparatus of the present invention positioned in an oropharyngeal region of a patient (shown in cross-section for clarity).

Fig. 2 shows a perspective view of an embodiment of the invention comprising a substantially solid walled cylindrical appliance.

Fig. 3 shows a perspective view of another 5 embodiment of the invention comprising a substantially mesh walled cylindrical appliance.

Fig. 4 shows a perspective view of an additional embodiment of the invention similar to the apparatus shown in Fig. 2, and including a recessed portion for 10 accommodating an epiglottis of a patient.

Fig. 5 shows a perspective view of yet another embodiment of the invention including an extended portion.

Fig. 6 shows a perspective view of a further 15 embodiment of the invention comprising a coiled appliance.

Figs. 7, 8 and 9 show, in perspective view, various other embodiments of the invention comprising substantially cuff-shaped appliances of different 20 proportions to accommodate different patient needs.

Fig. 10 shows a perspective view of still another embodiment of the invention comprising a substantially cuff shaped embodiment comprising a mesh material.

Fig. 11 a perspective view shows a yet further 25 embodiment of the invention comprising a substantially solid C-shaped appliance having apertures for allowing tissue ingrowth.

Fig. 12 shows a perspective view of an alternate embodiment of the invention that comprises a flat 30 flexible member including spaced apart struts extending between rounded end portions.

Figs. 13-16 show, in plan view, other alternate

D-3077

embodiments of the invention similar to the embodiment shown in Fig. 12.

Figs. 17-21 show, in plan view, various other alternative embodiments of the invention comprising a 5 single loop element.

Figs. 22-23 show, in plan view, yet other embodiments of the invention.

Fig. 24 shows a side view of a preferred embodiment of the invention in which the apparatus comprises an 10 elongated element structured to be at least partially submucosally implanted in the pharyngeal region of a patient.

Fig. 24a shows an alternative cross section of an embodiment of the invention similar to the embodiment 15 shown in Fig. 24, comprising multiple, spaced apart elongated elements at least partially submucosally implanted within the oropharyngeal region of a patient.

Fig. 25 shows a plan view of the embodiment of the invention shown in Fig. 24

20 Fig. 25a and 25b show cross-sectional views of alternative cross-sectional shapes of the embodiment of the invention shown in Fig. 25.

Figs. 26-28 each show a simplified view of the oropharyngeal region having various apparatus of the 25 invention submucosally implanted therein.

Detailed Description of the Invention

In a broad aspect of the invention, the apparatus generally comprise an appliance sized and structured to 30 be placed in a given position in an oropharyngeal region of a human or animal patient, other than to facilitate a surgical procedure on said patient, and being effective

D-3077

- in treating sleep apnea and/or snoring of said patient. The appliance is further effective, when so placed in the given position, to provide at least one additional benefit or advantage relative to a device sized and 5 structured for placement in a different position in a human or animal wherein a "different position" is defined as a position other than the given position.

Incorporated herein by this specific reference is the entire disclosure of each of the following patents:

- 10 Fraser et al U.S. Patent No. 5,571,135, Turnland U.S. Patent No. 5,360,401, Winston et al U.S. Patent No. 5,306,294, Heyn et al U.S. Patent No. 5,201,757, Burton et al U.S. Patent No. 5,078,720, Termin et al U.S. Patent No. 5,071,407, Porter U.S. Patent No. 5,064,435,
- 15 Wallstén et al U.S. Patent No. 5,061,275, Burton et al U.S. Patent No. 5,026,377, Savin et al U.S. Patent No. 4,950,227, Imbert U.S. Patent No. 4,875,480, Wallstén et al U.S. Patent No. 4,848,343, Wallstén et al U.S. Patent No. 4,732,152, Garza et al U.S. Patent No. 4,665,918,
- 20 Gould et al U.S. Patent No. 4,572,186, Strecker U.S. Patent No. 6,485,524 B2, Klumb et al U.S. Patent No. 6,488,700 B2, Klumb et al U.S. Patent No. 6,248,122 B1, Klumb et al U.S. Patent No. 6,238,430 B1, Harada et al U.S. Patent No. 5,037,427, McNamara et al U.S. Patent
- 25 No. 5,147,370, Kolobow et al U.S. Patent No. 6,027,516, Thorud et al U.S. Patent No. 6,019,779, Holman U.S. Patent No. 5,980,533, St. Germain U.S. Patent No. 5,836,966, Klein U.S. Patent No. 5,797,952, Gunderson U.S. Patent No. 5,776,142, Summers et al U.S. Patent No.
- 30 5,772,668, Lukic et al U.S. Patent No. 5,709,703, Lenker et al U.S. Patent No. 5,683,451, Bergentz et al U.S. Patent No. 3,993,078, Myler et al U.S. Patent No.

D-3077

- 5,474,563, Limon U.S. Patent No. 5,476,505, St. Germain et al U.S. Patent No. 5,534,007, Roberts et al U.S. Patent No. 5,603,698, Boatman et al U.S. Patent No. 5,632,771, Myler et al U.S. Patent No. 5,643,309,
5 Strecker U.S. Patent No. 6,485,524 B2, Augustine et al U.S. Patent No. 6,427,686 B2, Linder U.S. Patent No. 5,664,567, Downing U.S. Patent No. 4,821,715, Alfery U.S. Patent No. 6,386,199 B1, Lane et al U.S. Patent No. 5,494,029, Grosbois et al U.S. Patent No. 6,474,339 B1,
10 Bullard U.S. Patent No. 5,791,341, Gianturco U.S. Patent No. 4,580,568, Hart U.S. Patent No. 5,950,624, Zammit U.S. Patent No. 6,328,753 B1, Woodson U.S. Patent No. 6,161,541, Mark et al U.S. Patent No. 6,419,641 B1, Thompson et al U.S. Patent No. D458,679 S, Beyar et al
15 U.S. Patent No. 6,371,979 B1, Beyar et al U.S. Patent No. 6,371,953 B1, Thompson U.S. Patent No. 6,358,274 B1, Klima et al U.S. Patent No. 6,273,876 B1, Thompson U.S. Patent No. 6,254,631 B1, Thompson U.S. Patent No. 6,132,461, Thompson U.S. Patent No. 6,132,460, Vidlund
20 U.S. Patent No. 6,110,164, Beyar et al U.S. Patent No. 6,090,115, Vidlund et al U.S. Patent No. 6,033,394, Donadio, III U.S. Patent No. 6,027,863, Johnson et al U.S. Patent No. 6,022,343, Thorud et al U.S. Patent No. 6,019,779, Dustrude et al U.S. Patent No. 5,911,752,
25 Clubb et al U.S. Patent No. 5,815,904, Eliachar et al U.S. Patent No. 5,048,518, Conrad et al U.S. Patent No. 6,450,169, Bibi U.S. Patent No. 6,371,112, Thornton U.S. Patent No. 6,325,064, Thornton U.S. Patent No. 6,305,376, Thornton U.S. Patent No. 6,374,824,
30 Dutkiewicz U.S. Patent No. 6,257,236, Rittmann U.S. Patent No. 6,270,512, Thorner U.S. Patent No. 6,238,411, Hurbis U.S. Patent No. 6,106,541, Lundy, Jr. et al U.S.

D-3077

- Patent No. 6,098,616, Muchin U.S. Patent No. 6,058,931,
Filis U.S. Patent No. 6,004,342, Christopher U.S. Patent
No. 5,954,050, Boussignac U.S. Patent No. 6,363,935,
Muchin U.S. Patent No. 5,718,224, Conrad et al U.S.
5 Patent No. 6,250,307, Conrad et al U.S. Patent No.
6,401,717, Conrad et al U.S. Patent No. 6,390,096,
Berthon-Jones U.S. Patent No. 6,123,082, Halstrom U.S.
Patent No. 6,161,542, Halstrom U.S. Patent No.
5,868,138, Tielemans U.S. Patent No. 6,408,852, Shapiro
10 U.S. Patent No. 5,117,816, Bergersen U.S. Patent No.
6,129,084, Edwards et al U.S. Patent No. 6,126,657,
Edwards U.S. Patent No. 5,800,379, Edwards U.S. Patent
No. 5,738,114, Rotramel U.S. Patent No. 6,171,314,
Anderson U.S. Patent No. 5,893,365, Thomas U.S. Patent
15 No. 5,988,170, Gaumond et al U.S. Patent No. 6,379,311,
Belfer U.S. Patent No. 6,092,523, Richmond et al U.S.
Patent No. 6,345,202, Meyer et al U.S. Patent No.
6,329,352, Estes et al U.S. Patent No. 5,970,975,
Bourgeois et al U.S. Patent No. 6,126,611, Samelson U.S.
20 Patent No. 4,304,227, Dror U.S. Patent No. 4,198,967,
Gardy U.S. Patent No. 4,676,240, Meade U.S. Patent No.
5,682,903, Alvarez et al U.S. Patent No. 5,649,540,
Parks U.S. Patent No. 5,642,737, Hilsen U.S. Patent No.
5,611,355, Zammit U.S. Patent No. 6,183,493, Eliachar
25 U.S. Patent No. 4,794,924.

It has been discovered that a number of the devices disclosed in the above referenced patents, that are conventionally utilized or suggested for utilization in body regions other than the oropharyngeal region and/or 30 to treat conditions other than sleep apnea and/or snoring, can be utilized or modified to be utilized in the oropharyngeal region of a human or an animal in

order to treat sleep apnea and/or snoring, in accordance with the present invention. Any such modification or modifications to such conventional devices are considered to be included within the scope of the apparatus of the present invention. In addition, the use of any of such previous devices, and any modified such previous devices, in the oropharyngeal region of a human or an animal in order to treat sleep apnea and/or snoring is considered to be within the scope of the methods of the present invention. It can be noted that currently there are no stents marketed which are designed to expand to diameters in excess of 32 mm

For example, the at least one additional benefit or advantage of the apparatus of the present invention, relative to a device conventionally utilized or suggested for utilization in body regions other than the oropharyngeal region and/or to treat conditions other than sleep apnea and/or snoring, may comprise, without limitation, at least one or more of the following: the apparatus is structured to be located in the oropharyngeal region and to have an enhanced ability to be tolerated by the human or animal, for example, while the human or animal is awake or is naturally sleeping; the apparatus is structured to provide enhanced resistance to static collapsing forces of the oropharyngeal region and/or hypopharynx; the apparatus is structured to have an enhanced ability to allow for dynamic collapse; the apparatus is structured to have enhanced non-mobility, for example, upon coughing, throat clearing and/or sneezing; the apparatus is structured to have enhanced conformity to the healthy, normal shape of the pharynx; the apparatus is structured

D-3077

to have an enhanced ability to be removable; the apparatus is structured to have an enhanced ability to be deployable under direct vision via nasopharyngoscopy/laryngoscopy; and the like benefits.

5 In addition, the present apparatus preferably are structured to not substantially interfere with swallowing, respiration, vocalization, mucociliary function, epiglottis functioning and the like. The present apparatus are structured to maintain the
10 openness of the pharyngeal region during natural sleep.

Turning now to Fig. 1, a cross-sectional anatomical view of a human patient 1 is shown. The patient 1 has apparatus 10 in accordance with the present invention located within the patient's oropharyngeal region 1a in
15 order to treat, for example, control, reduce or even eliminate, the occurrence of sleep apnea and/or snoring.

Snoring and sleep apnea are often caused by a combination of narrowness and low muscle tone of the upper airways. The tongue 2a falls back and may obstruct
20 the airway, possibly leading to an arousal reaction and disturbing the normal sleeping pattern. Other portions of the oropharyngeal region may also collapse. For example, the lateral walls 2b of the oropharyngeal region often become excessively lax and block a free
25 flow of air during respiration. When the patient 1 is supine, for example, when the patient 2 is asleep and lying on his/her back, the relaxed tongue 2a moves inferior (down) and posterior (back), and/or the lateral walls 2b of the oropharyngeal region collapse inwardly
30 resulting in a narrower pharynx relative to when the patient 1 is upright. One cause for the narrowing of the pharynx in the supine position could be that the

oropharyngeal region 1a and hypopharyngeal region 1b, which have low consistencies, collapse because of lack of direct hard tissue support.

The apparatus 10 may be secured to the pharyngeal
5 region by various means. For example, the apparatus 10
may be sutured to the pharyngeal region, for example
with dissolvable sutures that will allow the apparatus
10 to be held in place while the apparatus 10 becomes
fixed to the region by means of tissue ingrowth.
10 Alternatively, the apparatus 10 may be secured to the
region by means of a suitable biocompatible adhesive as
are presently known in the art. Alternatively still,
the apparatus 10 may be secured to the region by being
surgically implanted into the region, for example,
15 directly beneath the region's mucosal layer,
(hereinafter, "submucosally"), for example, by being
pulled, with a surgical needle for example, into and
beneath the mucosal layer such that the apparatus at
least partially circumscribes the region.

20 The apparatus 10 of the present invention is
preferably designed to provide direct support to at
least some of these tissues when the patient 1 is supine
and asleep. For example, the apparatus 10 of the present
invention is structured so that when placed in the given
25 position in oropharyngeal region 1a, the apparatus 10
will push the tongue forward, and/or push the lateral
walls 2b away from one another thereby holding the
airway patent or open during the time the human or
animal is naturally sleeping.

30 As shown, the apparatus 10 may be sized and
structured to be positioned adjacent the epiglottis 2c
of patient 1, but preferably not in contact therewith.

D-3077

- For example, in one embodiment of the invention, the apparatus 10 is designed to overlay a posterior wall 2d of the oropharyngeal region 1a and provide an opening force outwardly against opposing lateral walls 2b of the oropharyngeal region 1a. In other embodiments of the invention, the apparatus 10 is designed to rest within a valeducular space 2e and provide a pushing force against the base 2f of the tongue 2a which makes up a portion of the anterior wall 2g of the oropharyngeal region 1a.
- 5 The valeducular space 2e, as the term is used herein, is defined as being the space between the anterior wall 2g of the throat and the upper tip 2h of the epiglottis 2c down to the conjunction of the epiglottis 2c with the anterior wall 2g of the pharynx.
- 10 In any event, the apparatus 10 is designed in such a manner as to substantially prevent same from interfering with the normal functioning of the tissue around the apparatus 10, particularly with the normal functioning of the epiglottis 2c. The apparatus 10 may include structures (described elsewhere herein) for anchoring or securing the apparatus 10 within the oropharyngeal region 1a in order to prevent the apparatus 10 from migrating away from or out of the given position.
- 15 Preferably, in all embodiments of the invention, the apparatus 10 is structured to closely and flexibly conform to the size and contours of at least a portion of the oropharyngeal region 1a.
- 20 In one useful embodiment, the apparatus 10 can be said to be effective to provide a support substantially equivalent to the support of tissue and/or muscles of an oropharyngeal region in a healthy, toned state.
- 25

As a specific example, the apparatus 10 may be sized and shaped to fit a human patient having a measured anterior-posterior linear distance between the pharyngeal walls, when the patient is awake and not 5 supine, and the tongue and/or other tissues are not fully lax.

The apparatus 10 is preferably structured to maintain a radial force or pressure, for example, a substantially constant radial force or pressure, against 10 the oropharyngeal region, specifically against the lateral walls of the oropharyngeal region, the posterior portion of the oropharyngeal region, and/or the base of the tongue. The pressure of the apparatus maintained against this region is advantageously sufficient to 15 maintain patency of the oropharyngeal region during natural sleep in a supine position (for example, greater than about 10 cm of water), and preferably exerts pressure less than that exerted by the surfaces of the oropharyngeal region during swallowing (for example, 20 about 400 cm of water). The apparatus preferably has a hoop strength in a range of about 5 cm water up to about 400 cm water. It is further noted that the design of apparatus 10 allows for variable hoop strength as measured along different points about the circumference 25 of the appliance of the apparatus.

The present apparatus 10 is designed and structured to allow substantially normal functioning of the oropharyngeal and pharyngeal regions, while maintaining the structural integrity of the apparatus over a long 30 period of time. An important consideration in the design of the present apparatus 10 includes the

D-3077

requirement that the apparatus 10 substantially maintain its structural integrity and strength despite the highly dynamic, peristaltic motion of the oropharyngeal and hypopharyngeal regions.

5 For example, it is known that a human being typically swallows an average of two times a minute, throughout the day. This equals around 2000 swallows per day. The force of the swallow varies from 1.5 lbs. to 6 lbs. of pressure, and the force lasts for about 0.1
10 to about 0.2 second.

Swallowing also includes the involuntary apposition of the soft palate to the posterior pharyngeal wall, which is believed to last almost a second and producing a pressure of about 160 millimeters of mercury and
15 initiates pharyngeal peristalsis, i.e. the wavelike muscular contractions that move food along the alimentary canal in the pharyngeal region. This moving front of contraction passes through the pharyngeal constrictors in sequence, traversing the pharynx and
20 hypopharynx at about 15 centimeters per second to reach the upper esophageal sphincter in about one second. The hypopharyngeal contraction lasts about 0.3 to about 0.5 second and generates an intraluminal pressure of 200 millimeters of mercury. The present invention is
25 designed to flex and contract along with this wave-like motion of the various muscles in the oropharyngeal and hypopharyngeal region.

The appropriate amount of force necessary to provide adequate support to maintain patency and
30 consistent air flow the oropharyngeal region during sleep, while allowing for the dynamic motion of the

D-3077

pharyngeal region and normal function of the oropharyngeal region and/or hypopharyngeal region, may vary between patients. Therefore, preferably the apparatus 10 is available in a range of radial forces 5 and sizes in order to suit different individuals. Preferably, each of the embodiments of the apparatus in accordance with the present invention are made of resilient and elastic biocompatible materials and all edges and surfaces are smooth and free of sharp 10 portions, burrs and contaminants.

Figs. 2-6 show various embodiments of the invention that are generally cylindrical or tubular in structure. Except as expressly described herein, each of the apparatus 10a, 10b, 10c, 10d and 10e, shown in Figs. 2-6 15 respectively, is similar to apparatus 10 and is structured, unless otherwise noted herein, to be utilized for the treatment of sleep apnea and/or snoring as hereinabove noted.

Turning now specifically to Fig. 2, apparatus 10a 20 is structured to fit substantially entirely within the oropharyngeal region and at least partially within the valecullar space and/or preferably extending no higher than the upper surface of the base of the tongue in the anterior portion of the apparatus. The posterior 25 portion of the apparatus may be designed to provide additional support above the oropharyngeal region.

The appliance 12 defines a central open or hollow space 12a and can be made of any suitable biocompatible material, for example, stainless steel, other metals, or 30 plastics (polymeric materials), and the like, and combinations thereof.

Fig. 3 shows an apparatus 10b in accordance with

- the present invention comprising a substantially cylindrical appliance 14 similar to appliance 12, with the most significant difference being that appliance 14 is comprised of a mesh, for example a woven wire mesh.
- 5 The mesh appliance 14 defines a central open or hollow space 14a and preferably comprises wires 14b made of a super-elastic material, for example, a nickel titanium alloy (to be described in more detail elsewhere herein), such as the alloy known as Nitinol.
- 10 Fig. 4 shows an additional apparatus 10c of the present invention, similar to apparatus 10a, comprising a solid cylindrical appliance 16 including a feature of a cut-out region 17 defined in the appliance 16, the cut-out region being appropriately sized, shaped, and positioned to accommodate natural movements and functions of the epiglottis of the patient. Thus, in this embodiment of the invention, apparatus 10c is fitted to a patient with cut-out portion 17 facing an anterior wall of the oropharyngeal region. The
- 15 epiglottis is therefore free to move inwardly and outwardly of the appliance by means of the cut-out region.
- 20 Fig. 5 shows yet another apparatus 10d of the present invention, comprising an appliance 18 having a relatively wider diameter distal or lower portion 19 which functions to anchor or hold the appliance 18 within the vallecular space. When in use, apparatus 10d is anchored at portion 19 within the vallecular space allowing the epiglottis to function normally within the
- 25 relatively wider hollow area defined by the lower portion 19.

30 Fig. 6 shows a further embodiment of the invention,

specifically an apparatus 10e generally comprising an appliance 20 having a helical or spiral spring including coils 22 comprising, for example, a super-elastic material, as described elsewhere herein.

5 Figs. 7-11 show various other embodiments of the invention that are generally non-circumferential in structure. Except as expressly described herein, each of the apparatus 10f, 10g, 10h, 10i and 10j, shown in Figs. 7-11 respectively, is similar to apparatus 10 and 10 is structured, unless otherwise noted herein, to be utilized for the treatment of sleep apnea and/or snoring as herein noted.

15 Turning now specifically to Fig. 7, the present invention preferably provides apparatus 10f, comprising an appliance 26 that is non-circumferential in structure. In other words, apparatus 10f, unlike apparatus 10a-10e, includes spaced apart end portions 27 defining a gap 32, and a closed portion 34. The end portions 27 are preferably rounded as shown.

20 More specifically, the appliance 26 may be described as comprising a substantially C-shaped member 35 defining a pair of resilient, flexible wire struts 36a and 36b connected at the end portions 27. The struts 36a and 36b may have any suitable transverse 25 cross-section, for example, a circular, oval, rounded, flattened or the like transverse cross-section. In this particular embodiment of the invention, the member 35 comprises a wire or ribbon that forms a continuous loop as shown, defining an open interior space 38.

30 Still referring to Fig. 7, the appliance 26 is structured to be positioned within the oropharyngeal region with the end portions 27 bearing against and

providing an opening force against the lateral walls of the oropharyngeal region. It is contemplated that the apparatus 10f may be alternatively positioned such that the appliance 34 rests substantially within or entirely 5 within the valedicular space and presses against the base of the tongue along closed portion 34.

Upon contraction of the oropharyngeal region, for example, during swallowing, the end portions 27 will be temporarily forced toward one another by the muscles in 10 the oropharyngeal region, and may or may not overlap or contact one another. The flexibility and relative spacing of the struts 36a and 36b allow the appliance 34 to contract and expand in the vertical direction as necessary, for example in conjunction with peristalsis 15 of the pharyngeal walls upon swallowing.

Preferably, each of the embodiments of the present invention is comprised of highly elastic, biocompatible materials. In particular, each of the non-circumferential apparatus in accordance with the present 20 invention preferably comprises a super-elastic material, more preferably, a nickel titanium (NiTi) alloy, such as the alloy known as Nitinol.

For general background purposes, a description of the benefits of Nitinol for use in the present invention 25 follows. Additional details of this alloy can be obtained from readily available sources and/or will be known to those of skill in the art.

Nickel titanium (also known as Nitinol) is in the class of materials known as shape memory alloys. A 30 thermoelastic martensitic phase transformation in the material is responsible for its extraordinary properties. These properties include the shape memory

effect, super-elasticity, and high damping capability.

Nitinol has the ability to absorb large amounts of strain energy and release it as the applied strain is removed. Nitinol also has excellent torqueability and 5 kink resistance, which is an important feature of the apparatus of the present invention due to the dynamic nature of the oropharyngeal and hypopharyngeal regions. Advantageously, super-elastic Nitinol alloys provide a substantially constant force over a large strain range.

10 The present apparatus more preferably comprise a Nitinol material, more preferably with a ratio of the two constituents, nickel and titanium, at about 50 atomic percent each (about 55 percent by weight of nickel).

15 The properties of Nitinol can be modified by changes in alloy composition, mechanical working, and heat treatment, as known to those of ordinary skill in the art. The specific alloy used in the apparatus of the present invention is selected mainly for its super-20 elastic effect rather than its shape memory effect.

Super-elastic Nitinol alloys preferably are used in the apparatus of the present invention to take advantage of a stress-induced martensitic transformation in order to achieve extreme amounts of flexibility and kink 25 resistance. It is known that an alloy of nickel and titanium can behave super-elastically if its Active A_f temperature is just below the use temperature. For example, alloys which are intended to be super-elastic at room temperature are generally produced with their 30 Active A_f temperatures just below room temperature in the range of about 0 to about 20°C. A super-elastic material will not be super-elastic at all temperatures, but will

D-3077

exhibit good super-elastic properties in a temperature window extending from the Active A_f temperature up to a temperature which is about 50°C above Active A_f . Therefore, a material with an Active A_f of about 15°C 5 will exhibits good super-elasticity up to about 65°C which means that the material will exhibit good super-elasticity at both room temperature and body temperature (37°C).

Nitinol is the more preferred material for the 10 apparatus of the present invention also due to its excellent biocompatibility, very high corrosion resistance, and excellent cytocompatibility. In addition, the nickel in nickel/titanium alloy is chemically joined to the titanium in a strong 15 intermetallic bond, so the risk of reaction, even in patients with nickel sensitivity, is extremely low. Additional details on nickel titanium alloys are known to those of ordinary skill in the art and are provided, for example, in Jervis, U.S. Patent No. 6,306,141, which 20 is incorporated herein in its entirety by this specific reference.

Figs. 8-10 show alternative embodiments of the invention similar to the embodiment shown in Fig. 7 in that the appliance is non-circumferential as defined 25 elsewhere herein.

More specifically, referring to Fig. 8, an apparatus 10g in accordance with the invention is shown that generally comprises a cuff-shaped appliance 50. Like appliance 26, appliance 50 includes spaced apart 30 end portions 27g defining a gap 32g, and closed portion 34g. A substantial distinction between apparatus 10g

D-3077

and apparatus 10f is that apparatus 10g comprises relatively wide, opposing outer peripheral portions 56a and 56b, that define flattened bands, rather than struts 36a and 36b. The outer peripheral portions 56a and 56b 5 define an open interior space 58. Relative to apparatus 10f, this particular design generally allows greater surface contact with oropharyngeal tissues as well as greater hoop strength or opening pressure.

Fig. 9 shows an apparatus 10h of the invention 10 comprising a cuff-shaped appliance 60 similar to appliance 50 for accommodating a patient with different needs, for example, a patient having a longer, more narrow oropharyngeal region. Appliance 60 includes spaced apart end portions 27h defining a gap 32h and 15 closed portion 34h.

Fig. 10 shows another apparatus 10i in accordance with the invention, the apparatus 10i being similar to the embodiment shown in Fig. 8. A significant distinction between apparatus 10i and apparatus 10g is 20 that the apparatus 10i comprises a substantially mesh structure for providing increased flexibility and/or to facilitate tissue ingrowth to restrict or prevent migration of the apparatus 10i. For example, the appliance 64 comprises an outer peripheral portion 66 25 made of a woven mesh wire for example, defining an interior space 68.

Fig. 11 shows yet another apparatus 10j in accordance with the present invention, comprising a non-circumferential cuff-shaped appliance 82 having spaced 30 apart end portions 27j defining a gap 32j. A significant distinction between apparatus 10j and apparatus 10g is that appliance 82 does not include

interior space 58, but is instead substantially solid as shown. In addition, appliance 82 preferably includes one or more through apertures 87 for facilitating tissue ingrowth.

5 Figs. 12-21 show various embodiments of the invention that are generally planar when in a resting or non-deployed state, for example, when the apparatus is located outside of the oropharyngeal region of a patient in a rest position. Except as expressly described
10 herein, each of the apparatus 10k, 10m, 10n, 10p and 10q, 10s, 10t, 10u, 10v and 10w shown in Figs. 12-21 respectively, is similar to apparatus 10 and is structured, unless otherwise noted herein, to be utilized for the treatment of sleep apnea and/or snoring
15 as herein noted.

Turning now to Fig. 12, apparatus 10k, in accordance with the present invention, generally comprises an appliance 110 having a flat, or substantially planar configuration (represented by phantom lines) that is flexible to achieve an arched, or curved configuration (shown in solid line). Like the embodiments of the invention shown in Figs. 7-11, the apparatus 10k defines a non-circumferential configuration when in the deployed state.

25 More particularly, the appliance 110 comprises a body portion 112 and end portions 114 spaced apart by the body portion 112. The appliance 110 may be in any suitable form, such as, for example, a substantially rectangular (shown in Fig. 12), a substantially circular
30 form, a substantially oblong form, a substantially oval form or a substantially elliptical form or the like

D-3077

configuration. When located in the oropharyngeal region, the appliance 110 is structured to exert a sufficient force, more preferably a sufficient substantially constant radial force, on the 5 oropharyngeal region, particularly against the lateral walls of the oropharyngeal region, to maintain or cause the airway passing through the region to be patent, so that it is substantially open or unobstructed.

The appliance 110 is structured to take on a 10 deployed configuration when located within the oropharyngeal region such that the end portions 114 are spaced apart from each other by other than the body portion 112. For example, the end portions 114 may be spaced apart by the epiglottis or a portion of the 15 anterior or posterior wall of the oropharyngeal region. The apparatus 110 is structured to be sufficiently resilient and flexible to allow for normal dynamic movement or motion of the oropharyngeal region with little or no loss in desirable properties, such as hoop 20 strength and the like, over an extended period of wear.

Advantageously, the apparatus 10k may be formed entirely from a unitary flat sheet of material that is laser cut into the desired configuration. Using a flat elastic or super-elastic sheet of material or a sheet 25 pre-curved to a diameter larger than that of the oropharyngeal region of the human or animal, the apparatus 10k, once implanted into the oropharyngeal region, applies substantially continuous opening pressure to the oropharyngeal walls, for example, the 30 lateral walls of the oropharyngeal region.

Appliance 110 may have a length of between about

D-3077

50mm and about 90 mm in the substantially flat configuration, and a height of between about 15 mm and about 25 mm. The dimensions of appliance 110 are selected based on individual patient need. The 5 appliance is designed such that the effective non-constrained diameter of the appliance, when deployed, is greater than about 32 mm.

Appliance 110 comprises a plurality of flexible wire or ribbon struts 140, which preferably extend 10 between the radiused end portions 114 extending along a substantial portion of the length of the appliance 110. For example, the appliance 110 may comprise between about 2 and about 50 struts or more, and preferably between about 6 and about 20 struts, such as about 10 15 struts.

In the embodiment shown in Fig. 12, each of the struts 140 has a thickness of about 0.005 inch and a width of about 0.010 inch. This design has been found to provide the required flexibility and resiliency in at 20 least three dimensions or directions of motion, and preferably, in addition, twisting motion, without exhibiting significant fatigue over an extended period of wear/time in service requiring dynamic movement, such as in the oropharyngeal region.

25 The number, thickness, and width of the struts 140 may be varied to produce a desired opening pressure (e.g., hoop strength) on the base of the tongue or to reduce or increase the surface area of the struts 140 which are in contact with the oropharyngeal walls. This 30 design also allows improved vertical collapse/deformation of the oropharyngeal region, for

D-3077

example, allowing peristalsis type movement during swallowing.

When provided in an oropharyngeal region of a patient for the treatment of sleep apnea and/or snoring, 5 the appliance 110 is curved with a convex surface pressing against the tissues to be supported, particularly the lateral walls of the oropharyngeal region and/or the base of the tongue.

The appliance 110 is structured to be self-expanding with a controlled length during such expansion. This can be achieved by suitable selection 10 of super-elastic materials, preferably Nitinol, and appropriate selection of strut length and other dimensions. The appliance 110 also is preferably 15 structured to have a relativelyatraumatic nature of all surfaces thereof and of the curved end portions. In addition, the appliance 110 is structured to exhibit the ability to be delivered in a minimal diameter access manner by rolling the appliance 110 onto itself within a 20 catheter, inserter tube and the like.

The appliance 110 may be tailored to be effective in a variety of patients and in a variety of different body regions that would benefit from the consistent support provided by such an appliance. For example, the 25 size and structure of the appliance can be selected to accommodate a specific need. The amount of force provided by the appliance can be modified by appropriate selection of the number of struts, width and/or thickness of struts, and/or surface area covered by the 30 struts and/or the like factors. Generally, as the struts become thinner and take up less surface area, the

D-3077

appliance 110 will become more compliant and will move and flex with less radial force exerted thereby and will flex to a greater extent without permanent deformation. It is noted that a portion of appliance 110 may be 5 modified such that it will function to anchor or secure the appliance in place. For example, an outer or peripheral strut 140a may be configured to achieve a "fluted" configuration. In some embodiments, although not shown, one or more of the struts may be shaped as 10 wave forms or s-shapes. In yet other embodiments, although not shown, cushioned end members may be provided on the end portions 114 of the appliance 110 in order to enhance comfort and/or proper fit.

An optional feature of the invention is shown at 15 141 for facilitating anchoring of the apparatus 10k in the given position. More specifically, at least one of the struts 140b may be configured to form barbed portions 145a and 145b for enhancing secure attachment of the appliance 110 to the posterior wall of the 20 oropharyngeal region. It is also contemplated that other means for securing the apparatus 10k in the given position may be provided, for example, surfaces of the apparatus 10k may be coated with a biologically compatible glue or adhesive.

Fig. 13 shows another apparatus 10m including 25 appliance 210 for treating sleep apnea and/or snoring, in accordance with the present invention. Apparatus 10m is similar to apparatus 10k, with an additional feature shown on apparatus 10m being the addition of spacing 30 portions 242, positioned and structured to maintain a spaced apart relationship between adjacent struts 240

D-3077

when apparatus 10 is in the oropharyngeal region of a patient. Appliance 210 includes end portions 214 and body portion 212.

Figs. 14 and 15 show apparatus 10n and 10p respectively, for treating sleep apnea and/or snoring, in accordance with the present invention. Apparatus 10n and apparatus 10p are similar to apparatus 10k and 10m, with the most significant distinction being that, apparatus 10n and 10p are substantially oval or 10 elliptical rather than rectangular in shape. Apparatus 10n generally comprises appliance 310 including rounded end portions 314 joined by body portion 312, and a plurality of spaced apart struts 340. Apparatus 10p generally comprises appliance 410 including rounded end 15 portions 414 joined by body portion 412, and a plurality of spaced apart struts 440 and spacing portions 442.

Fig. 16 shows yet another apparatus 10q for treating sleep apnea and/or snoring in accordance with the present invention. As shown, apparatus 10q 20 comprises an appliance 510 having a substantially elliptical shape and including a plurality of bowed or arched struts 545 that converge at end portions 514.

Turning now specifically to Figs. 17-21, additional alternative embodiments of the present invention are 25 shown. Like the embodiments of the invention shown in Figs. 12-16, these embodiments are typically planar in structure when at rest and not deployed in the oropharyngeal region of a patient. A significant distinction between the embodiments shown in Figs. 12-16 30 and the alternative embodiments shown in Figs. 17-21, is that the latter embodiments each preferably define a

single continuous loop.

More specifically, Fig. 17 shows an apparatus 10s for treating sleep apnea and/or snoring in accordance with the present invention, comprising a substantially cross-shaped appliance 610, defined by a single loop element 612. The appliance 610 preferably is cut, more preferably photoetched, from a single sheet of material, preferably a sheet comprising a Nitinol superelastic alloy material, and preferably having a sheet thickness of about 0.01 inch to about 0.1 inch. Element 612 preferably has a substantially uniform width of between about 1 mm to about 5mm or greater. The appliance 610 preferably has a height H along a vertical axis of about 15 mm to about 25 mm, and a length L along a horizontal axis of about 60mm to about 90 mm allowing an effective non-constrained diameter of greater than about 32 mm. The cross-shaped appliance 610 preferably is symmetrical about its vertical and horizontal axes. Appliance 610 includes vertical portions 616a and 616b each defining an angle α , and horizontal portions 618a and 618b each defining an angle β .

For purposes of example only, not to be considered limiting the scope of the present invention, vertical portions 616a and 616b define a peak-to-peak measurement (i.e. height H) of about 25 mm, and horizontal portions 618a and 618b define a peak-to-peak measurement (i.e. length L) of about 70 mm. Also for purposes of this specific example only, each of vertical portions 616a and 616b defines an angle α of about 15° and each of horizontal portions 618a and 618b defines an angle β of about 6°.

Appliance 610 is structured to be placed in the oropharyngeal region in a position such that horizontal portions 618a and 618b rest against and provide support to the lateral walls of the oropharyngeal region. The 5 vertical axis of the apparatus 610, generally defined by vertical portions 616a and 616b, are disposed against or adjacent the posterior wall of the oropharyngeal region.

Fig. 18 shows yet another apparatus 10t for treating sleep apnea and/or snoring in accordance with 10 the present invention. Apparatus 10t is similar to apparatus 10s in that it is defined by a single loop element 712 cut from a single sheet of material, for example, a Nitinol alloy. A substantial distinction between apparatus 10s and apparatus 10t is that, rather 15 than comprising a cross-shaped appliance 610, apparatus 10t comprises a substantially X-shaped appliance 710 having a length L and a height H. Appliance 710 includes multiple leg portions 717a, 717b, 717c and 717d extending from a generally central region 720, wherein 20 paired leg portions 717a and 717c and paired leg portions 717b and 717d, both define an angle ϕ .

For purposes of this specific example only, not to be considered limiting the scope of the present invention, appliance 710 has a length L of about 70 mm 25 and a height H of about 25 mm, and angle ϕ is about 36°.

Appliance 710 is structured to be placed in the oropharyngeal region in a position such that leg portions 717a, 717b, 717c and 717d rest against and provide support to the lateral walls of the 30 oropharyngeal region, and the generally central portion 720 is disposed against or adjacent the posterior wall

of the oropharyngeal region.

Fig. 19 shows yet another apparatus 10u for treating sleep apnea and/or snoring in accordance with the present invention. Apparatus 10u is similar to apparatus 10s in that it is defined by a single loop element 812 cut from a single sheet of material, for example, a Nitinol alloy. Apparatus 10u comprises an appliance 810 having a relatively narrow, generally central body portion 814 (having height H_1) terminating at relatively wide end portions 816a and 816b (having height H_2), and a length L. End portions 816a and 816b preferably define angle γ as shown.

For purposes of this specific example only, not to be considered limiting the scope of the present invention, appliance 810 has a length L of about 85 mm, a height H_1 of about 10 mm, a height H_2 of about 35 mm, and an angle γ of about 75°. Element 812 has a width W_1 at generally central portion 814 and a width W_2 of about 5 mm at end portions 816a and 816b.

Appliance 810 is structured to be placed in the oropharyngeal region in a position such that end portions 816a and 816b rest against and provide support to the lateral walls of the oropharyngeal region, and the generally central body portion 814 is disposed against or adjacent the posterior wall of the oropharyngeal region.

Fig. 20 shows yet another apparatus 10v for treating sleep apnea and/or snoring in accordance with the present invention. Apparatus 10v comprises an appliance 910 comprising loop element 912, and including a generally central body portion 914, and multiple end

D-3077

portions 916a, 916b, 916c and 916d. As shown adjacent end portions define an angle η . Appliance 910 further includes a vertical portion 950 that defines an angle δ .

Appliance 910 is structured to be placed in the
5 oropharyngeal region in a position such that multiple end portions 916a, 916b, 916c and 916d rest against and provide support to the lateral walls of the oropharyngeal region, and the generally central body portion 914 is disposed against or adjacent the
10 posterior wall of the oropharyngeal region.

Fig. 21 shows yet another apparatus 10w for treating sleep apnea and/or snoring in accordance with the present invention. Apparatus 10w comprises an appliance 1010 that is somewhat similar to appliance 910
15 in that appliance 1010 includes a generally central body portion 1014 and multiple end portions 1016a, 1016b, 1016c and 1016d. Appliance 1010 has somewhat different proportions, including a relatively wide upper central portion 1019 that is configured to provide enhanced
20 tissue support to portions of the posterior wall of the oropharyngeal region, relative to tissue support provided by appliance 910.

Figs. 22-23 show other embodiments of the invention for treating sleep apnea and/or snoring. Like the
25 embodiments of the invention shown in Figs. 12-22, these embodiments are typically planar in structure when at rest and not deployed in the oropharyngeal region of a patient.

Fig. 22 shows an apparatus 10x in accordance with
30 the invention comprising a substantially symmetrical appliance 1110 including a substantially linear body

D-3077

portion 1112 and a plurality of struts 1118 extending from the body portion 1112, for providing support to the oropharyngeal tissues. The number and length of struts 1118 preferably are selected based on a particular patient need. For purposes of example only, appliance 1110 may have an upper portion 1120 having about two pairs of struts 1118 defining a tip to tip length L_1 of about 62 mm, and a lower portion 1122 having about five pairs of struts 1118 defining a tip to tip length L_2 of about 82 mm.

Fig. 23 shows an apparatus 10y in accordance with the invention that is similar to apparatus 10x. The most significant distinction is that apparatus 10y comprises an appliance 1210 that includes a body portion 1212 and struts 1218 that are offset from one another along body portion 1212.

Turning now to Fig. 24, a preferred embodiment of the invention is shown, generally at 10z. Apparatus 10z is similar to apparatus 10a through apparatus 10x in that apparatus 10z is structured to be effective in maintaining patency of the airway of a patient 1, for example, the oropharyngeal region 1a of a patient. However, apparatus 10z is specifically structured to be at least partially, and in some cases substantially entirely submucosally, implantable into the pharyngeal region, for example the oropharyngeal region, of the patient.

Apparatus 10z, more clearly shown in Fig. 25, preferably comprises a single elongated element 1401 having end portions, for example, rounded end portions 1406 and a body portion 1408 extending or connected

therebetween.

As shown, end portions 1406 are preferably structured to facilitate implantation, for example, surgical implantation, of the element 1401. For 5 example, end portions 1406 may include appropriately sized apertures 1410 for receiving suturing thread. The element 1401 may have a rounded cross-section such as shown in Fig. 25a, or a polygonal cross section, for example a rectangular cross section, such as shown in 10 Fig. 25b.

Referring still to Fig. 25, element 1401 preferably has a length L of between about 50 mm and about 70 mm and a width W of between about 2 mm or less and about 6 mm. Dimensions of the appliance 1400 may be at least in 15 part based upon, for example, the size or diameter of the patient's pharyngeal region and the specific portion of the pharyngeal region to be supported by the apparatus 10z. A typical area of support as mentioned elsewhere herein, is the area encompassing, at least, a 20 portion of one or more of the lateral walls of the oropharyngeal region.

Appliance 1400 preferably comprises Nitinol, Dacron®, or other suitable, flexible, elastic biocompatible material as discussed elsewhere herein.

25 Advantageously, the element 1401 is designed to be surgically implantable in the pharyngeal region, at least partially circumscribing the region, and at least partially, preferably substantially entirely, beneath the mucosal layer thereof. The appliance 1400 may also 30 be at least partially sutured to the pharyngeal tissues, for example, at end portions 1401a of the element 1401.

D-3077

and/or secured to the oropharyngeal tissues by means of a biocompatible adhesive.

Turning now to Fig. 26, appliance 1400 is shown sized to be placed at least partially circumscribing an 5 interior hollow passage (representing a cross-section of the airway of the patient) defining the pharyngeal region. This view (as well as views shown in Fig. 27 and Fig. 28) is a simplified representation of a cross-section of the oropharyngeal region 1a, with posterior 10 wall 2d and anterior wall 2g, (which includes the base 2f of the tongue 2a) and opposing right and left lateral walls 2b. This placement of appliance 1400 is effective in providing support to the lateral walls 2b of the oropharyngeal region 1a. The appliance 1400 is shown 15 substantially entirely submucosally implanted.

Turning now to Fig. 27, appliance 1400 is shown sized to be placed circumscribing, at least one full circumference of, the interior hollow space defined by the pharyngeal region. In this case, the appliance 1400 20 is sized to traverse the base 2f of the tongue 2a, for example, beneath the mucosal tissue thereof. The appliance 1400 is shown partially submucosally implanted.

Fig. 24a shows another apparatus, generally at 25 10za, in accordance with the present invention. Apparatus 10za is substantially similar to apparatus 10z, except that apparatus 10za comprises an appliance 1400a including a plurality of elongated, spaced apart elements, for example at least two, or three or even 30 more spaced apart elements 1401a, 1401b, and 1401c, depending upon the specific needs of a particular

D-3077

patient. Except as indicated elsewhere herein, it is to be appreciated that elements 1401a, 1401b and 1401c are structured to be placed, for example, at least partially submucosally, implanted in a manner as described 5 hereinabove with respect to element 1401.

Each element 1401a, 1401b, and 1401c may be substantially, entirely independent, or unitary, in structure with respect to each other element 1401a, 1401b, and 1401c. Alternatively, the multiple elements 10 1401a, 1401b, and 1401c may be secured to each other by suitable means, for example, suturing, wire, ribbon or the like, for substantially maintaining the spaced apart relationship between the elements 1401a, 1401b, 1401c when the elements 1401a, 1401b, 1401c are positioned 15 within and secured to the pharyngeal region.

In a related embodiment of the invention, a method is provided for maintaining patency of a pharyngeal region. Particularly, the method may comprise the step of at least partially submucosally placing at least one 20 elongated element within the pharyngeal region, for example the oropharyngeal region in one or more strategic locations, wherein the placement thereof will cause the region to be stiffened or strengthened against collapse during natural sleep.

25 To illustrate another optional feature of the present invention, Fig. 28 shows a simplified view of the oropharyngeal region 1a of a patient, having apparatus 10zb in accordance with an embodiment of the invention, submucosally implanted therein. Apparatus 30 10zb comprises one or more magnetic components 1500a and 1500b, structured and designed to be effective to

D-3077

provide a magnetic field useful for providing gentle, substantially constant and continuous resistance against collapse of the pharyngeal walls, particularly the lateral walls 2b of the oropharyngeal region 1a, for example during natural sleep, while allowing substantially normal functioning of the pharyngeal region, for example during swallowing.

In the example shown, the two magnetic components 1500a, 1500b are strategically placed within the 10 oropharyngeal region 1a such that like magnetic poles (i.e. repellent magnetic poles) are positioned substantially facing one another to create a magnetically repellent force therebetween (indicated in simplified form by arrows 1502). The repellent force 15 caused by the strategically placed magnetic components 1500a and 1500b is effective for providing an opening force within the oropharyngeal region, thereby maintaining patency of the region during natural sleep while still allowing constriction of the region during 20 swallowing.

It will be appreciated by those of skill in the art that not all possible variations of the apparatus for treating sleep apnea and/or snoring are shown, and that there are many other variations of the apparatus that 25 are structured and shaped to provide specific support to different areas of the pharyngeal region, for example, the oropharyngeal region in order to treat sleep apnea and/or snoring, and based on the specific needs of a particular patient. Each of these variations is 30 considered to be within the scope of the present invention.

In yet another broad aspect of the present invention, methods are provided for maintaining patency of a pharyngeal region, for example, the oropharyngeal region, in order to substantially reduce the occurrence 5 of sleep apnea and/or snoring. These methods in accordance with the invention comprise, for example, steps of strengthening, reinforcing and/or stiffening tissues of the region which are subject to collapse during natural sleep. For example, this may be 10 accomplished by any one or more of the following steps: injecting an agent into the tissues which will cause partial necrosis of portions of the tissues in the region, thereby stiffening the region; injecting, into the tissues, a liquid or gel agent that solidifies 15 within the region to provide a reinforcement against collapse of the region; mechanically or chemically irritating the tissues to cause a tissue reaction that firms the tissues of the region; and applying a wave energy to the tissues to cause a tissue reaction that 20 firms the tissues of the region, for example, but not limited to ultrasonic energy, radiofrequency energy, thermal energy (either adding thermal energy to the tissues or chilling the tissue by removing thermal energy). Combinations of two or more of these steps may 25 be advantageously employed.

A preferred method for maintaining patency of a pharyngeal region, in accordance with the present invention, generally comprises providing a member, for example elongated element 1401, in a substantially flat 30 or precurved configuration. The member has a body portion and end portions spaced apart by the body portion. The member is implanted, at least partially

submucosally, within the pharyngeal region, preferably the oropharyngeal region, such that the member is effective to provide a substantially constant force against at least a portion of each of the lateral walls 5 of the region.

Preferably, the step of implanting comprises implanting the member into the pharyngeal region such that the member is substantially entirely submucosally implanted in the pharyngeal region.

10 For example, the member may be implanted into oropharyngeal tissues, preferably directly beneath the mucosal layer, by using a curved surgical needle to weave the member into and beneath the submucosal tissue.

In another embodiment of the invention, the method 15 comprises the steps of providing an apparatus in the oropharyngeal region of the human or animal, for purposes other than surgery. The apparatus is effective in treating sleep apnea and/or snoring and/or in maintaining patency of the oropharyngeal region during 20 natural sleep of the human or animal, without causing substantial interference with one or more natural functions of the epiglottis.

Each of the apparatus for treating sleep apnea and/or snoring described and shown elsewhere herein are 25 suitable for use in the methods of the present invention. It is to be appreciated, however, that the apparatus used for performing the methods of the invention may take other forms as well. For example, it is contemplated herein that a conventional stent may be 30 used in maintaining the airway in the pharyngeal region, for example, the oropharyngeal region in an open state, and such use is considered to be within the scope of the methods of the present invention. The apparatus used in

D-3077

the methods of present invention may be devices, for example but not limited to, a conventional stent, sized and structured for placement in another region of the human or animal other than the pharyngeal region, for 5 example, the oropharyngeal region.

In another embodiment of the invention, a method for maintaining patency of a pharyngeal region of a patient comprises the steps of providing an apparatus in a first configuration, for example a rolled, coiled, or 10 otherwise deformed configuration; inserting the apparatus into the oropharyngeal region, for example through the oral or nasal cavity of the patient while the apparatus is in a first configuration; and, thereafter, allowing the apparatus to reconfigure or 15 expand to a deployed second configuration, for example a substantially cuff shaped, C-shaped, or other suitable deployed configuration, within the oropharyngeal region.

Any suitable deployment assembly useful for inserting the apparatus through the mouth or oral 20 cavity, or nasal cavity of a patient and into the oropharyngeal region may be utilized in accordance with the methods of the present invention.

For example, a suitable deployment assembly includes an outer tube (about 10 mm diameter) and inner 25 tube (about 8 mm diameter) disposed within the outer tube. A retaining clip may be used to fix the tubes in place with respect to each other. The appliance, for example in rolled form, is provided within the outer tube at a distal portion thereof. Graspers, having a 30 manually manipulable proximal portion may be provided through the tubes for assisting in positioning or

D-3077

removal of the appliance.

During insertion through the mouth or oral cavity of the patient, the deployment assembly is advanced past the tongue of the patient until the inner diameter of 5 the outer tube and the rolled appliance passes into the oropharyngeal region. The retaining clip is then removed from the inner tube. The graspers may be used to facilitate repositioning of the appliance as necessary or desirable. The appliance is deployed by 10 retraction of the outer tube. (The assembly/graspers may be used to later remove the appliance if desired).

In a more specific, related embodiment of the invention, the following method is provided. This method generally comprises the steps of providing a flat 15 or pre-curved member (for example, appliance 110, 210, 310, 410, 510, 610, 710, 810 910, 1010, 1110 or 1120 shown in the drawings), pulling end portions of the flat or pre-curved member together to form a folded member and holding or temporarily securing the end portions 20 together by means of a grasper, clamp, hemostat, suture (for example, a bioresorbable suture), and/or suitable means for temporarily holding the end portions together in contact with one another. The method further comprises the steps of placing the member in the folded 25 or pinched configuration, into the oropharyngeal region, for example by way of the oral or nasal cavity of the patient, and releasing the end portions, thereby allowing the member to expand radially within the oropharyngeal region to provide a substantially constant 30 radial force against the lateral walls of the oropharyngeal region and/or the base of the tongue.

D-3077

The method may further comprise the step of repositioning the member while the member is located within the oropharyngeal region and/or the step of removing the member therefrom. This may be accomplished 5 by folding the member into a rolled or pinched configuration and withdrawing the member from the body region.

EXAMPLE 1

10 A 40-year-old, 5-foot, 11 in., 350 lb male is referred by his primary care physician for evaluation of sleep disturbance. He experiences snoring with apneic pauses, and severe daytime hypersomnolence with narcolepsy, and has so for many years. His occupation as 15 a truck driver has been jeopardized by this behavior. Several years prior, he underwent uvulopalatoplasty (UPPP) and tonsillectomy, without any significant relief of his symptoms. The patient claims that the use of CPAP was attempted, but was unsuccessful.

20 A polysomnography is performed indicating a Respiratory Disturbance Index (RDI) of 113.4 with severe desaturations, bradycardia, and complete absence of stage 3, stage 4, and REM sleep. CPAP therapy was titrated to 18 cm of water, but the patient's RDI remained elevated 25 at 60 with ongoing, severe desaturations.

Appliance 1400 having a length of about 70mm and a width of about 1.0. mm and a thickness of about 0.0075 inches (about 0.2mm), is selected by the physician for submucosal implantation.

30 Under general anesthesia, and using direct laryngoscopy techniques, the appliance is introduced into the submucosal tissues beginning in the right lateral pharyngeal region, particularly the right lateral oropharyngeal region. The appliance is introduced

D-3077

submucosally using a curved surgical needle which is used to carefully pull the appliance into the tissues in a manner that causes the appliance to be substantially concealed within the tissues, with little or no exposure
5 of any portion of the appliance postsurgically.

The appliance is guided medially, and inferiorly, traveling around the posterior oropharyngeal region and ultimately into the submucosal tissues of the tongue base. The tongue base is then traversed and the
10 appliance is brought back along the right lateral oropharyngeal wall. The appliance thus makes at least one complete rotation around the pharynx. Careful microscopic examination of the pharyngeal tissues reveals no areas of appliance exposure. Extubation proceeds
15 without difficulty, and the patient is closely observed overnight.

During the first week of recovery, the patient reports having some desire to cough out the device, throat pain, dysphagia, and hoarseness.

20 However, by the end of the first week, these symptoms are reported as minimal. Further, the patient indicates a significant reduction in effort, wheezing, and noise during daytime breathing. A CT Scan is performed to confirm adequate device placement and
25 integrity. A modified barium swallow study is obtained at the end of the second week. This study indicates that the appliance is intact, allowing normal swallowing in the pharyngeal region and appears to be providing circumferential support to the oropharyngeal region.

30 Polysomnography is repeated at two weeks, showing significant improvements in oxygen saturations and RDI.

EXAMPLE 2

A 50 year old, 5 foot 4, 180 pound, female patient
35 complains of severe hypersomnolence. It is additionally noted that the patient's spouse has longed complained of

D-3077

the patient's substantial nightly snoring and has witnessed pauses in the patient's breathing followed by gasping for air when she sleeps (believed to be apneic pauses).

5 Following clinical tests and evaluation of patient history, the patient is diagnosed with severe sleep apnea.

An appliance 1400 is selected for implantation in the patient. In this example, the appliance 1400 is made 10 of Nitinol and has a length of about 40 mm, a width of 1.25 mm and a thickness of about 0.5 mm.

Under general anesthesia, and using direct laryngoscopy techniques, the appliance is introduced into the submucosal tissues beginning in the right lateral 15 oropharyngeal region. The appliance is then guided medially, and inferiorly, traveling around the posterior oropharyngeal region and ultimately into the submucosal tissues of the left lateral oropharynx. The appliance does not traverse the tongue. The appliance thus makes 20 about a 180 degree rotation around the oropharynx.

Careful microscopic examination of the oropharyngeal tissues reveals no areas of appliance exposure. Extubation proceeds without difficulty, and the patient is closely observed overnight.

25 Within two weeks, the patient reports feeling more energy during the daytime and alertness upon awakening. Her husband remarks that the patient's snoring has substantially decreased and she does not seem to be experiencing apneic pauses during the night.

30 While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.